Medicines & Healthcare products
Regulatory Agency

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United Kingdom
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[redacted]

3 March 2025

MHRA reference: **FOI2025/00101**

Dear [redacted]

Thank you for your information request, which we received on 6 February. You asked for:

"We would like to request the following documents related to XGEVA 120 mg solution for injection in pre-filled syringe (PLGB 13832/0091) approved by MHRA under the International Recognition Procedure.

1) Assessment report of reference regulator EMA for this product under the procedure number EMEA/H/C/002173/II/0082/G.
2) Clinical study report [including all its appendix(ces)] of clinical study conducted by the Sponsor/Applicant to support assessment and approval of XGEVA 120 mg/mL solution for injection in pre-filled syringe."

MHRA Response

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

In response to your request we can confirm that the only data submitted with the application for XGEVA 120 mg solution for injection in pre-filled syringe (PLGB 13832/0091) was Module 3 (Quality data), the assessment of which is commercially sensitive. We therefore consider this information to be exempt under Section 41(2) (Information provided in confidence) and Section 43(1) and 43(2) (Commercial interests) of the Freedom of Information (FOI) Act.

This is in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency – see the below-linked document, where it states that this information is commercially confidential information (CCI):

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HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION (europa.eu)

Section 41(1) - information provided in confidence
This is an absolute exemption and no consideration of the public interest is required. The withheld information was provided to the MHRA in confidence by a third-party for the purposes of assessment. This information has the necessary quality of confidence as it is more than trivial and not otherwise accessible; the preservation of confidences is recognised by the courts to be an important matter and one in which there is a strong public interest. In this case, the information was provided to the MHRA with explicit conditions on its use by the MHRA (including further disclosure) and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the party who provided the information. In such circumstances, our view is that disclosure would be an actionable breach of that confidence, and this engages the Section 41(1) exemption.

Section 43(1) and 43(2) – commercial interests
Release of the information would be likely to cause harm to the third party's commercial interests. We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information. As a qualified exemption, this exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released.

XGEVA 120 mg solution for injection in pre-filled syringe (PLGB 13832/0091) was approved as a line extension of the existing product (XGEVA 120 mg solution for injection PLGB 13832/0046), the approval was supported by acceptable evidence of the quality of the new formulation of denosumab in a pre-filled syringe.

No new clinical data was submitted with this application. The clinical studies for the original product are described in the European Public Assessment Report (EPAR) as published by the European Medicines Agency (EMA). This can be found using the following link Xgeva, INN-denosumab

The assessment of this application also approved changes to the product information, for example, the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL). However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

However, to be helpful you can find the information at:
SPC - Microsoft Word - 2677224956131701818_spc-doc.doc
PIL - 818488f2c50fa78aaf88ad86966652557d7b987b

This concludes our response to your request.

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If you have a query about this response, please contact us at foi.request@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group

Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF